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**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

☒ Declaration Submitted with Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number SHA-19-CIP2

First Named Inventor Shalaby

COMPLETE IF KNOWN

Application Number

Filing Date

03/01/2002

Art Unit

Examiner Name

As the below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Coated, Slow-absorbing Textile Constructs for Sutures and Tissue Engineering

(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY)

as United States Application Number or PCT International

Application Number

and was amended on (MM/DD/YYYY)

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

[Page 1 of 2]

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent ApplicationDirect all correspondence to: ☒Customer Number
or Bar Code LabelOR ☐

Correspondence address below

PATENT & TRADEMARK OFFICE

Name

Address

City

State

ZIP

Country

Telephone

Fax

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR :

☐ A petition has been filed for this unsigned inventor

Shalaby W.
Given Name
(first and middle [if any])

Shalaby
Family Name
or Surname

Inventor's
Signature

02/28/2002

Date

Anderson

S.C.

USA

USA

Residence: City

State

Country

Citizenship

6309 Hwy-187

Mailing Address

City

ANDERSON

State

SC

ZIP

29625

Country

USA

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any])

Family Name
or Surname

Inventor's
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

City

State

ZIP

Country

☐ Additional inventors are being named on the ____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Shalaby
 Application No./Patent No.: _____ Filed/Issue Date: 3-1-2002
 Entitled: Coated, Slow-absorbing Textile Constructs for Sutures...
Poly-Med, Inc, a corporation
 (Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
 2. ☐ an assignee of less than the entire right, title and interest.
 The extent (by, percentage) of its ownership interest is _____ %

in the patent application/patent identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____
 The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
 The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
3. From: _____ To: _____
 The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

[] Additional documents in the chain of title are listed on a supplemental sheet.

- [☒] Copies of assignments or other documents in the chain of title are attached.
 [NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

3-1-2002
 Date

Shalaby W. Shalaby
 Typed or printed name
Shalaby W. Shalaby
 Signature
PRESIDENT & DIRECTOR of R&D
 Title

[illegible]

WASHINGTON, DC 20231,
ON March 17, 1999
SAID ENVELOPE HAVING AN EXPRESS MAIL
MAILING LABEL OF: EE 789 565 359 US
Leigh Gregory

3. All statements made herein of my own knowledge are true and

all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR: Shalaby W. Shalaby

INVENTOR'S SIGNATURE:

Shalaby W. Shalaby

DATE OF EXECUTION:

3/16/99

CITIZENSHIP:

U.S.A.

RESIDENCE ADDRESS:

6309 Hwy 187
Anderson, S.C. 29625

1006642-030100

03-26-1999



100995011

EXPRESS MAIL CERTIFICATE

I HEREBY CERTIFY THAT THIS CORRESPONDENCE
IS BEING DEPOSITED WITH THE UNITED STATES
POSTAL SERVICE AS EXPRESS MAIL, POSTAGE
PREPAID, IN AN ENVELOPE ADDRESSED TO:
COMMISSIONER OF PATENTS AND TRADEMARKS,
WASHINGTON, DC 20231,
ON March 17, 1999
HAVING AN EXPRESS MAIL LABEL NO. OF
EE789565359US

Leigh P. Gregory
LEIGH P. GREGORY

Jc541 U.S. PTO
60/124838
03/17/99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shalaby

Docket No.: SHA-19

Serial No.:

Group Art Unit:

Filing Date: March 17, 1999

Title: High Strength Fibers of l-Lactide Copolymers, ε-Caprolactone, and Trimethylene Carbonate and Absorbable Medical Constructs Thereof

ASSIGNMENT COVER SHEET (37 CFR 3.31)

Honorable Commissioner of
Patents and Trademarks
Washington, DC 20231

Attn: Assignment Branch

Sir:

Attached please find an Assignment document for recordation.

1. This Assignment is for the following patent application and/or issued patent:

Serial No.:

Filed on:

Patent No.:

Issued:

which was previously assigned:

Reel:

Frame:

The party conveying this interest: Shalaby W. Shalaby, 6309 Hwy 187, Anderson, SC 29625.

2. The rights are being conveyed to:

03/25/1999 DNGUYEN 00000249 60124838

01 FC:581

40.00 OP

[illegible]

4. Please address correspondence to:

5. The attached assignment was executed on: March 16, 1999

- X is in the English language.

7. Submitted herewith is:

- _____ a true copy of the original document

- b. The fee for recordal (37 CFR 1.21 (h)) is \$40.00. A check for \$40.00 payable to the Commissioner of Patents and Trademarks is included herewith.

9. This document is filed in duplicate.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Respectfully submitted,



Leigh P. Gregory
Attorney for Applicants
Registration No. 33,241

3300-D North Main Street
Anderson, SC 29621
(864) 964-0090

March 17, 1999
DATE

20100501 21000001

ASSIGNMENT OF WORLDWIDE RIGHTS

WHEREAS, I, Shalaby W. Shalaby, a citizen of the United States, residing at 6309 Highway 187, Anderson, SC 29625, as assignor, have made an invention entitled High Strength Fibers of l-Lactide Copolymers, ε-Caprolactone, and Trimethylene Carbonate and Absorbable Medical Constructs Thereof as described in a provisional patent application for U.S. Letters Patent, which is about to be filed in the U.S. Patent and Trademark Office; and

WHEREAS, POLY-MED, INC. a body politic and corporate under the laws of the State of South Carolina, whose post office address is 511 Westinghouse Road, Pendleton, South Carolina, 29670; as assignee, is desirous of securing the entire, right, title, and interest in and to this invention in all countries throughout the world, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for and in consideration of the sum of One Dollar (\$1.00) in hand paid and other good and valuable consideration the receipt of which from assignee is hereby acknowledged, I, as assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States which may be granted thereon, and all reissues thereof, and all rights to claim priority on the basis of such application, and all applications for Letters Patent which may hereafter be filed for this invention in any foreign country and all Letters Patent which may be granted on this invention in any foreign country, and all extensions, renewals, and reissues thereof, and I hereby authorize and request the Commissioner of Patents of the United States and any official of any foreign country whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to

10066412-030102

assignee, its successors and assigns, in accordance with the terms of this Assignment.

AND, I HEREBY covenant that I have the full right to convey the interest assigned by this Assignment, and I have not executed, and will not execute any agreement in conflict with this Assignment;

AND, I HEREBY further covenant and agree that I will, without further consideration, communicate with assignee, its successors and assigns, any facts known to me respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title of this invention in said assignee, its successors and assigns, execute all rightful oaths and generally do everything possible to aid assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States and any foreign country, it being understood that any expense incident to the execution of such papers shall be borne by the assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hands,

Shelby W. Shelby
3/16/99
Date

1008949-630400

EXPRESS MAIL CERTIFICATE

I HEREBY CERTIFY THAT THIS CORRESPONDENCE
IS BEING DEPOSITED WITH THE UNITED STATES
POSTAL SERVICE AS AN EXPRESS MAIL, POSTAGE
PREPAID, IN AN ENVELOPE ADDRESSED TO:
COMMISSIONER OF PATENTS AND TRADEMARKS,
WASHINGTON, DC 20231,
ON March 17, 1999
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MAILING LABEL OF: EE789565359US

Leigh P. Gregory
LEIGH P. GREGORY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shalaby

Docket No.: SHA-19

Serial No.:

Group Art Unit:

Filing Date:

Title: High Strength Fibers of l-Lactide Copolymers, ε-
Caprolactone, and Trimethylene Carbonate and Absorbable
Medical Constructs Thereof

SUBMISSION OF VERIFIED STATEMENTS TO ESTABLISH
SMALL ENTITY STATUS

Honorable Commissioner of
Patents and Trademarks
Washington, DC 20231

Sir:

The attached statements are being submitted to establish small entity
status in this

- ☒ provisional patent application
☐ patent

by the:

- a. ☒ independent inventor 37 CFR 1.9(c) and 1.27(b)
b. ☐ non-inventor supporting
claim by another 37 CFR 1.9(c) and 1.27(b)
c. ☒ small business concern 37 CFR 1.9(d) and 1.27(c)
d. ☐ non-profit organization 37 CFR 1.9(e) and 1.27(d)

Reg. No. 33,241

Leigh P. Gregory
Signature of Attorney

Leigh P. Gregory
3300-D North Main Street
Anderson, SC 29621

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shalaby

Docket No.: SHA-19

Serial No.:

Group Art Unit:

Filing Date:

Title: High Strength Fibers of L-Lactide Copolymers, ε-Caprolactone, and Trimethylene Carbonate and Absorbable Medical Constructs Thereof

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9 (f) and 1.27 (c)) - SMALL BUSINESS CONCERN

I hereby declare that I am an official of and am empowered to act on behalf of the small business concern identified below:

NAME OF CONCERN: POLY-MED, INC.
ADDRESS OF CONCERN: 6309 Hwy 187
Anderson, SC 29625

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed, to and remain with the small business concern identified above with regard to the invention, entitled High Strength Fibers of L-Lactide Copolymers, ε-Caprolactone, and Trimethylene Carbonate and Absorbable Medical Constructs Thereof, by inventor Shalaby W. Shalaby described in the above-referenced patent application.

The rights held by the above identified small business concern are exclusive.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of

entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

3/16/99
Date

S.W. Shalaby
Name S. W. SHALABY

PRESIDENT

Title

6309 Hwy-187

Address

ANDERSON, S.C.

City, State

1006649-030102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shalaby

Docket No.: SHA-19

Serial No.:

Group Art Unit:

Filing Date:

Title: High Strength Fibers of L-Lactide Copolymers, ϵ -Caprolactone, and Trimethylene Carbonate and Absorbable Medical Constructs Thereof

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9 (f) and 1.27 (b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled High Strength Fibers of L-Lactide Copolymers, ϵ -Caprolactone, and Trimethylene Carbonate and Absorbable Medical Constructs Thereof described in

☒ the provisional application filed herewith.
- application serial no. 0 / _____, filed _____.
- patent no. _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, convey, or license any rights in the invention is listed below:

- no such person, concern, or organization
☒ persons, concerns or organizations listed below

FULL NAME Poly-Med, Inc.
ADDRESS 6309 Hwy 187, Anderson, SC 29625

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of

entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Shalaby W. Shalaby

Shalaby W. Shalaby
Signature of Inventor

Date 3/16/99

1065312-097109